

# **EXHIBIT 1**

**UNITED STATES COURT OF APPEALS  
FOR THE THIRD CIRCUIT**

---

No. \_\_\_\_\_

---

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION

---

ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

---

DEFENDANTS' PETITION FOR PERMISSION TO APPEAL PURSUANT TO  
FEDERAL RULE OF CIVIL PROCEDURE 23(f)

---

Jessica Davidson Miller (Admitted to Practice in Maryland and the District of Columbia; Not Admitted in New York)

*Additional counsel and parties listed  
on signature page*

*Liaison Counsel for Manufacturer*

*Defendants*

SKADDEN, ARPS, SLATE,

MEAGHER & FLOM LLP

One Manhattan West

New York, NY 10001

Telephone: (212) 735-3000

Facsimile: (917) 777-2588

jessica.miller@skadden.com

*Attorney for Zhejiang Huahai*

*Pharmaceutical Co., Ltd., Huahai U.S.,*

*Inc., Princeton Pharmaceutical Inc., and*

*Solco Healthcare U.S., LLC*

## TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION .....	1
QUESTIONS PRESENTED.....	2
STATEMENT OF THE CASE.....	2
REASONS FOR GRANTING THE PETITION.....	5
I. THE CERTIFICATION OF MEDICAL-MONITORING CLASSES WAS ERRONEOUS. ....	5
A. The District Court’s Order Ignores Factual Variations And Contravenes <i>Gates And Barnes</i> . ....	6
B. The District Court Independently Erred In Ignoring Legal Variations. ....	9
II. THE DISTRICT COURT’S CERTIFICATION OF ECONOMIC- LOSS CLASSES WAS ERRONEOUS. ....	12
A. Individualized Legal Issues Predominate.....	12
B. Individualized Factual Issues Also Predominate. ....	14
C. A Class Action Is A Vastly Inferior Mechanism For Resolving The Dispute. ....	20
CONCLUSION.....	23

## **TABLE OF AUTHORITIES**

### **Page**

### **FEDERAL CASES**

<i>In re American Medical Systems</i> , 75 F.3d 1069 (6th Cir. 1996) .....	21
<i>Barnes v. American Tobacco Co.</i> , 161 F.3d 127 (3d Cir. 1998) .....	5, 6, 8, 9
<i>In re Bridgestone/Firestone, Inc.</i> , 288 F.3d 1012 (7th Cir. 2002) .....	18
<i>Brown v. Electrolux Home Products, Inc.</i> , 817 F.3d 1225 (11th Cir. 2016) .....	14
<i>Center City Periodontists, P.C. v. Dentsply International, Inc.</i> , 321 F.R.D. 193 (E.D. Pa. 2017) .....	17
<i>City of St. Petersburg v. Total Containment, Inc.</i> , 265 F.R.D. 630 (S.D. Fla. 2010).....	19
<i>Cole v. General Motors Corp.</i> , 484 F.3d 717 (5th Cir. 2007) .....	12
<i>Elson v. Black</i> , 56 F.4th 1002 (5th Cir. 2023) .....	13
<i>Farrar &amp; Farrar Dairy, Inc. v. Miller-St. Nazianz, Inc.</i> , 254 F.R.D. 68 (E.D.N.C. 2008) .....	18
<i>In re Ford Motor Co. Vehicle Paint Litigation</i> , 182 F.R.D. 214 (E.D. La. 1998) .....	19
<i>Gates v. Rohm &amp; Haas Co.</i> , 655 F.3d 255 (3d Cir. 2011) .....	passim

<i>Gianino v. Alacer Corp.</i> , 846 F. Supp. 2d 1096 (C.D. Cal. 2012).....	14
<i>Grandalski v. Quest Diagnostics Inc.</i> , 767 F.3d 175 (3d Cir. 2014) .....	13, 14
<i>In re Hydrogen Peroxide Antitrust Litigation</i> , 552 F.3d 305 (3d Cir. 2008) .....	16, 17
<i>Laudato v. EQT Corp.</i> , 23 F.4th 256 (3d Cir. 2022) .....	5
<i>Lexecon Inc. v. Milberg Weiss Bershad Hynes &amp; Lerach</i> , 523 U.S. 26 (1998).....	21
<i>Marshall v. H&amp;R Block Tax Services</i> , 270 F.R.D. 400 (S.D. Ill. 2010) .....	21
<i>Muehlbauer v. General Motors Corp.</i> , No. 05-2676, 2009 WL 874511 (N.D. Ill. Mar. 13, 2009).....	14
<i>In re National Prescription Opiate Litigation</i> , 956 F.3d 838 (6th Cir. 2020) .....	11
<i>In re National Prescription Opiate Litigation</i> , 976 F.3d 664 (6th Cir. 2020) .....	11, 23
<i>Newton v. Merrill Lynch, Pierce, Fenner &amp; Smith, Inc.</i> , 259 F.3d 154 (3d Cir. 2001) .....	20
<i>In re NHL Players’ Concussion Injury Litigation</i> , 327 F.R.D. 245 (D. Minn. 2018) .....	9, 10
<i>Pilgrim v. Universal Health Card, LLC</i> , 660 F.3d 943 (6th Cir. 2011) .....	12, 13
<i>In re Rezulin Products Liability Litigation</i> , 210 F.R.D. 61 (S.D.N.Y. 2002).....	17

<i>Rodriguez v. National City Bank</i> , 726 F.3d 372 (3d Cir. 2013) .....	5
<i>In re St. Jude Medical, Inc.</i> , 425 F.3d 1116 (8th Cir. 2005) .....	9
<i>Sutton v. St. Jude Medical S.C., Inc.</i> , 419 F.3d 568 (6th Cir. 2005) .....	10
<i>Travelers Indemnity Co. v. Dammann &amp; Co.</i> , 594 F.3d 238 (3d Cir. 2010) .....	10
<i>In re Valsartan-Nitrosodimethylamine (NDMA) Contamination Products Liability Litigation</i> , 363 F.Supp.3d 1378 (J.P.M.L. 2019) .....	3
<i>Vista Healthplan, Inc. v. Cephalon, Inc.</i> , No. 2:06-cv-1833, 2015 WL 3623005 (E.D. Pa. June 10, 2015) .....	21
<i>In re Zantac (Ranitidine) Products Liability Litigation</i> , --- F.Supp.3d ----, 2022 WL 17480906 (S.D. Fla. Dec. 6, 2022) .....	8

## STATE CASES

<i>Donovan v. Philip Morris USA, Inc.</i> , 914 N.E.2d 891 (Mass. 2009) .....	10
<i>Hansen v. Mountain Fuel Supply Co.</i> , 858 P.2d 970 (Utah 1993) .....	11
<i>Petito v. A.H. Robins Co.</i> , 750 So. 2d 103 (Fla. Dist. Ct. App. 2000) .....	11
<i>Sinclair v. Merck &amp; Co.</i> , 948 A.2d 587 (N.J. 2008) .....	11

## FEDERAL STATUTE

28 U.S.C. § 1407 .....	11
------------------------	----

## **INTRODUCTION**

The district court’s sweeping order, certifying both economic-loss and medical-monitoring classes—including 111 hastily grouped consumer and third-party payor (“TPP”) subclasses—ignored well-established Third Circuit law in a transparent attempt to exert settlement pressure on defendants. Nowhere does the court explain how any trial involving 428 separate products, made and sold by 28 different defendants, involving claims governed by the laws of 52 separate jurisdictions, could possibly be feasible. Nor does the court differentiate its two multistate medical-monitoring classes from those that this Court has repeatedly rejected, let alone address this Court’s skepticism that medical-monitoring classes could *ever* be certified in light of the individualized issues implicated by medical testing protocols. *See Gates v. Rohm & Haas Co.*, 655 F.3d 255, 268 (3d Cir. 2011). Instead, the court elides or downplays individualized issues and massive manageability problems in the name of “promoting Class Action settlement” (D.2261 (“Opinion”) 41), effectively taking the position that the rigorous requirements of Rule 23 can (and should) be bent in MDL proceedings.

If allowed to stand, the district court’s ruling would eviscerate this Court’s prior class action holdings and Rule 23(b)(3)’s predominance and superiority requirements and suggest that MDL judges in this Circuit have carte blanche to ignore the dictates of Rule 23.

## **QUESTIONS PRESENTED**

1. Whether the district court erred in certifying a 47-state medical-monitoring class even though: (a) exposure to the alleged carcinogenic impurities in generic valsartan-containing drugs (“VCDs”) varied; (b) there is no scientifically established threshold at which exposure to nitrosamines increases cancer risk; and (c) the relevant state laws are materially different?

2. Whether the district court erred in certifying an “economic loss” class comprising more than 100 subclasses and 52 jurisdictions’ laws and implicating individualized facts regarding reliance, causation, materiality and loss?

## **STATEMENT OF THE CASE**

Facts. Between July 2018 and January 2019, several manufacturers voluntarily recalled 428 hypertension medications containing valsartan, due to the presence of trace amounts of N-Nitrosodimethylamine (“NDMA”) and/or N-Nitrosodiethylamine (“NDEA”), two nitrosamine impurities. (*E.g.*, D.2012, 1-2.)

The medications at issue were manufactured in different facilities using different processes and varied widely in their impurity levels, but in all cases, any risk of cancer was extremely remote, leading the U.S. Food and Drug Administration (“FDA”) to emphasize that patients should continue taking their VCDs until alternatives were available and that the risk of not taking VCDs “greatly outweighs the potential risk of exposure to trace amounts of

nitrosamines.” (*Id.* 2.) Nevertheless, lawsuits followed. The Judicial Panel on Multidistrict Litigation transferred many of the lawsuits to the U.S. District Court for the District of New Jersey for coordinated proceedings before Judge Robert B. Kugler in 2019, *see In re Valsartan-Nitrosodimethylamine (NDMA) Contamination Prods. Liab. Litig.*, 363 F.Supp.3d 1378 (J.P.M.L. 2019), after which plaintiffs filed consolidated class action complaints (D.121, D.123).

Plaintiffs’ Class-Certification Motions. Briefing on class certification commenced in November 2021. Plaintiffs moved for certification of nationwide and multistate classes asserting claims for: (1) consumer economic loss; (2) TPP economic loss; and (3) medical monitoring.

*Consumer Economic Loss.* The consumer plaintiffs, individuals who were prescribed and purchased VCDs, claim that the medications were worthless due to the alleged presence of NDMA or NDEA. These plaintiffs proposed a three-phase class trial involving 93 proposed subclasses of individuals. (*E.g.*, D.2008, 2.)

The TPP plaintiffs do not consume prescription drugs and are not at risk of harm from drug impurities. (*E.g.*, D.2010, 1.) Rather, TPPs pay for a portion (or all) of consumer prescription costs under prescription drug insurance plans. (*Id.*) The TPP plaintiffs contend that all TPPs are entitled to full refunds for all VCD payments between 2012 and 2019 because the medications were rendered worthless by the alleged presence of NDMA or NDEA. (*Id.*)

*Medical Monitoring.* Plaintiffs moved to certify two medical-monitoring classes. The first—a 28-jurisdiction class—sought to assert medical-monitoring causes of action. (D.2012, 2.) The second—a 49-jurisdiction class—sought to recover medical monitoring as a form of relief for nine distinct product liability theories. (*Id.*) Plaintiffs defined both classes to include individuals “who consumed a sufficiently high Lifetime Cumulative Threshold [LCT] of NDMA, NDEA, or other nitrosamine, in generic valsartan-containing drugs manufactured by or for Defendants ... since January 1, 2012.” (*Id.*)

Decision Below. The MDL court certified nearly all of plaintiffs’ proposed classes, including a consumer economic-loss class with 93 subclasses and a TPP class with 18 subclasses. (Opinion 9.) Among its rationales, the court found that this massive nationwide class structure “concentrates litigation efforts for both parties into fewer trials as well as promoting Class Action settlement.” (*Id.* 41.)

The District Court’s Prior Statements About Settlement. The district court’s statement regarding settlement is consistent with its longstanding, expressed desire for a global resolution of the valsartan litigation. In 2019, the court announced its intention to “talk[] to [the parties] early and often about settlement possibilities” (D.77, 3/27/2019 Hr’g Tr. 29:13-30:8), and in early 2022, it imposed on the parties the unusual obligation to retain separate counsel whose role was exclusively to discuss settlement with two appointed special masters (D.1848, 1/5/2022 Hr’g Tr.

20:12-22:20). A short time later, the court told the parties that it intended to instruct the two special masters to “begin aggressively scheduling some sessions” to discuss settlement, in advance of briefing on class certification. (D.1946, 2/28/2022 Hr’g Tr. 43:2-13.)

### **REASONS FOR GRANTING THE PETITION**

This Court applies a “more liberal standard” than other circuits in granting interlocutory review under Rule 23(f). *Laudato v. EQT Corp.*, 23 F.4th 256, 260 (3d Cir. 2022) (citing *Rodriguez v. Nat’l City Bank*, 726 F.3d 372, 376-77 (3d Cir. 2013)). Under that standard, review is appropriate where, inter alia, “the district court’s class certification determination was erroneous,” “the appeal might facilitate development of the law on class certification,” or certification “risks placing inordinate ... pressure on defendants to settle.” *Id.* Review is justified here under any of these separate grounds.

#### **I. THE CERTIFICATION OF MEDICAL-MONITORING CLASSES WAS ERRONEOUS.**

Medical-monitoring classes generally “founder for lack of cohesion” if they are brought under Rule 23(b)(2), or for lack of factual predominance if they are brought under Rule 23(b)(3). *Gates*, 655 F.3d at 264, 270 (affirming denial of certification of medical-monitoring class under Rules 23(b)(2) and 23(b)(3)); *see also Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 143 (3d Cir. 1998) (affirming denial of certification of Rule 23(b)(2) medical-monitoring class). This is so

because an individual's need for monitoring and whether such a need was caused by the defendant's alleged conduct are highly individualized questions that turn on each proposed class member's individual characteristics. Indeed, this Court has questioned whether "the necessity for individuals' medical monitoring regimes can" *ever* "be proven on a class basis." *Gates*, 655 F.3d at 268; *see also Barnes*, 161 F.3d at 146.

If such a case exists, this is not it. The district court ignored overwhelming factual and legal variations that plainly preclude certification under this Court's precedents.

**A. The District Court's Order Ignores Factual Variations And Contravenes *Gates* And *Barnes*.**

The district court disregarded patently individualized factual questions concerning causation and medical necessity—two issues that this Court has repeatedly held preclude class treatment of medical-monitoring claims.

The medical-monitoring plaintiffs argued that predominance/cohesiveness were satisfied because anyone exposed to nitrosamines in VCDs above the proposed LCTs would have a heightened risk of cancer, justifying monitoring. But plaintiffs pulled the LCTs from thin air; they are not reliably derived through science and rest instead on the unsupported general causation opinions of two experts, neither of whom actually performed an LCT analysis, and one of whom made clear that there is *no bright line threshold* for NDMA or NDEA

carcinogenicity. (D.1750-3, Ex. C, 90.) Moreover, plaintiffs' LCTs vary widely based on class members' different medication dosages, durations of exposure, and the specific VCDs taken. Plaintiffs do not even posit a method to identify which class members satisfy these thresholds, much less to prove on a classwide basis that any heightened risk of cancer experienced by these individuals was the result of exposure to trace amounts of nitrosamines in VCDs as opposed to other factors. Exposure to carcinogens can occur through lifestyle choices (e.g., tobacco use); naturally occurring phenomena (e.g., ultraviolet light); medical treatments (e.g., immunity-suppressing drugs); occupational and household exposures; and even age. (D.2009-16, Ex. 190, ¶ 83.)

Certification was impossible on these facts. As this Court held in *Gates*, a plaintiff must be able to show a single exposure that "would create a significant risk of contracting a serious latent disease for all class members." 655 F.3d at 267; *see also id.* at 268 (class treatment improper where plaintiffs failed to "account[] for the age of the class member being exposed, the length of exposure, [and] other individual factors such as medical history"). Plaintiffs cannot do that here. Even the district court recognized that the "scientific community itself cannot tease out a single, individual cause of cancer from a lifetime of nitrosamine exposure from various sources"; "[n]or can [it] determine the cause of an inflection point making one's likelihood of developing cancer more and more probable." (Opinion 64-65.)

Although the court went on to conclude that “a probable increase in cancer development is attributable to an increase in exposure to nitrosamines—via VCD ingestion, inhalation, etc.” (*id.* 65), that simplistic conclusion (even if true)<sup>1</sup> falls miles short of the causation showing that is required to certify a medical-monitoring class. *See Gates*, 655 F.3d at 267; *Barnes*, 161 F.3d at 145 (medical-monitoring class could not be certified because “plaintiffs cannot prove causation by merely showing that smoking cigarettes causes cancer and other diseases” but must also show that “nicotine manipulation caused *each individual plaintiff* to have a significantly increased risk of contracting” disease) (emphasis added).

Individualized questions of medical necessity also precluded certification. As plaintiffs’ own expert acknowledged, testing and treatment decisions in a clinical setting are based on the “patient’s specific situation,” including medical history, comorbidities and the patient’s subjective desires. (D.2009-7, Ex. 50, 51:19-52:11.) This is particularly true because some of the screening proposals

---

<sup>1</sup> Another MDL court recently excluded plaintiffs’ general causation experts’ opinions in litigation involving nitrosamine impurities in heartburn medications, explaining, in a detailed ruling that spanned hundreds of pages, that there was no reliable science to support the claim that the impurities posed a risk to users. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, --- F.Supp.3d ----, 2022 WL 17480906 (S.D. Fla. Dec. 6, 2022), *appeal filed*. The district court here, by contrast, denied defendants’ *Daubert* motions on general causation in a perfunctory three-page order. (D.1958.) When it was presented with the *Zantac* order in a motion for reconsideration, the district court immediately and summarily denied the motion, without requiring a response from plaintiffs. (D.2210.)

themselves (such as endoscopy and biopsy) pose risks to class member health. (See D.2009-25, Ex. 201, 16, 18); *Gates*, 655 F.3d at 269. Although the district court noted in passing that “defendants raise doubts whether a proposed medical monitoring program is medically necessary” (Opinion 65), it never analyzed those concerns or explained how they could be sufficiently overcome to justify certification.<sup>2</sup>

In short, as in *Gates* and *Barnes*, the elements of “causation and medical necessity” “require individual proof,” *Gates*, 655 F.3d at 264; *see also Barnes*, 161 F.3d at 145-46, and the district court grossly erred in overlooking those problems and certifying a medical-monitoring class.

**B. The District Court Independently Erred In Ignoring Legal Variations.**

The court doubled its error by ignoring legal variations within the certified medical-monitoring classes despite widespread judicial recognition that there are fundamental “[d]ifferences in state laws on medical monitoring.” *See, e.g., In re St. Jude Med., Inc.*, 425 F.3d 1116, 1122 (8th Cir. 2005) (reversing certification); *In re NHL Players’ Concussion Injury Litig.*, 327 F.R.D. 245, 260, 266 (D. Minn.

---

<sup>2</sup> The district court also ignored the fact that VCDs manufactured by Mylan and Aurobindo (or by Teva, using Mylan’s active pharmaceutical ingredient (“API”)) contained only NDEA impurities – not NDMA. Individuals who took those medications were included in the medical-monitoring classes, which would screen for a number of cancers that are only alleged to be linked to NDMA.

2018) (denying certification of proposed multi-state medical-monitoring class under Rule 23(b)(3) because “individualized legal issues will substantially predominate over common legal issues”).

The district court thought otherwise, finding that Table 7 accompanying its order “sufficiently accommodates the state law variability” issues raised by defendants. (Opinion 61.) But that table at most purports to divide the relevant states according to whether their laws recognize medical monitoring as an independent claim or a remedy, and whether they require a present physical injury. (*See id.* Table 7.) Even if the district court had properly divided the class along those lines (it did not),<sup>3</sup> it failed to address other fundamental variations, including the necessary showing of injury (i.e., whether subcellular injury suffices), *see Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 901-02 (Mass. 2009);

---

<sup>3</sup> The table erroneously lumps multiple jurisdictions (e.g., Alaska, Idaho and Hawaii) into the independent medical-monitoring class regardless of whether those states have “any court decisions that clearly address the issues related to medical monitoring,” *NHL*, 327 F.R.D. at 262, and similarly includes states (e.g., Tennessee) in the remedy class where the law regarding medical monitoring is unclear, *see Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 n.7 (6th Cir. 2005) (describing Tennessee law as “murky”). Attached to the Opinion is a confusing appendix that asserts, *inter alia*, that a state without any medical-monitoring law “is just as likely to allow [medical monitoring] as not allow[] it.” (Opinion, App. A.) Such an expansion of state law by a federal court violates Third Circuit precedent, too. *See Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 253 (3d Cir. 2010) (“‘[W]here two competing yet sensible interpretations’ of state law exist, ‘we should opt for the interpretation that restricts liability, rather than expands it.’”).

whether a treatment for the disease exists, *see Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993); the available detection procedures, *see Petito v. A.H. Robins Co.*, 750 So. 2d 103, 106-07 (Fla. Dist. Ct. App. 2000); whether monitoring is limited to toxic tort cases, *see Sinclair v. Merck & Co.*, 948 A.2d 587, 591, 594-95 (N.J. 2008); or the widely varying state laws that govern the underlying negligence and product-liability claims asserted in the remedy class. (See D.2012-2, App. B.)

The district court also offered no plan for properly instructing a lay jury on these varying legal standards. Instead, it announced that any problems with the workability of the proposed medical-monitoring classes could be solved by “th[e] [c]ourt’s expertise and experience” overseeing the MDL. (Opinion 66.) That was yet further error; “[t]he rule of law applies in multidistrict litigation ... just as it does in any individual case,” *In re Nat’l Prescription Opiate Litig.*, 956 F.3d 838, 841 (6th Cir. 2020), including with regard to class certification, *see In re Nat’l Prescription Opiate Litig.*, 976 F.3d 664, 670 (6th Cir. 2020) (reversing certification of negotiation class, which was “designed to fundamentally alter the nature of the MDL—to foster settlement through a novel means of class action”). The fact that cases have been coordinated for pre-trial proceedings under 28 U.S.C. § 1407 does not vitiate the requirements imposed by the Federal Rules of Civil Procedure.

For this reason, too, the district court erred in certifying plaintiffs’ medical-monitoring classes.

## **II. THE DISTRICT COURT’S CERTIFICATION OF ECONOMIC-LOSS CLASSES WAS ERRONEOUS.**

The district court also erred in certifying two nationwide economic-loss classes because: (1) individual legal issues arising out of 52 jurisdictions’ laws governing five separate causes of action (i.e., 260 legal frameworks) swamp any common legal issues; (2) the court failed to evaluate and credit fact and expert evidence highlighting the individualized nature of issues such as reliance, causation, injury and damages; and (3) there is no practical way to hold a trial involving so many defendants and varying legal regimes.

### **A. Individualized Legal Issues Predominate.**

“[I]n a class action governed by the laws of multiple states ... , ‘variations in state law may swamp common issues and defeat predominance.’” *Cole v. Gen. Motors Corp.*, 484 F.3d 717, 724 (5th Cir. 2007). Nationwide classes—even those pursuing only one cause of action—are particularly poor candidates for class treatment because legal differences will generally “cast a long shadow over any common issues of fact plaintiffs might establish.” *Pilgrim v. Universal Health Card, LLC*, 660 F.3d 943, 946 (6th Cir. 2011) (upholding order striking nationwide class at outset of case).

Nothing about this case makes it an exception to that rule. If anything, it presents even greater complications than the typical nationwide class, spanning 52 jurisdictions, alleging not one but five causes of action, and seeking certification of classes brought by not just one but two types of plaintiffs: consumers and TPPs. Multiplied together, these variations mean that hundreds of legal frameworks could potentially apply to the economic-loss claims at issue in this litigation.

The district court apparently believed that creating a “chart of state law jurisprudence” and splintering the class into 111 subclasses (one of which includes class members from 30 states) would “reduce the overall variability of individualized plaintiffs’ legal issues.” (Opinion 22, 40.) But the term “[s]ubclass” is not a magic word that remedies defects of predominance.” *Elson v. Black*, 56 F.4th 1002, 1007-08 (5th Cir. 2023). Rather, plaintiffs must demonstrate that “each subclass independently satisfie[s]” Rule 23 and “*how* [the] proposed subclasses would alleviate ... obstacles to certification.” *Id.*; *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014) (“significant burden to demonstrate that grouping is a workable solution”).

Even if the groupings adopted by the court accurately reflected the relevant state laws (they do not), there would be 111 legal variations to consider in a single proceeding—more than double the amount deemed unfeasible by other courts. *Pilgrim*, 660 F.3d at 946; *Elson*, 56 F.4th at 1006-07. Moreover, the subclasses do

not address issues of reliance and causation, which vary from one jurisdiction to the next, and therefore cannot overcome Third Circuit precedent precluding certification of multistate classes where the states at issue impose “varying elements of reliance ... and causation.” *Grandalski*, 767 F.3d at 183; *see Gianino v. Alacer Corp.*, 846 F. Supp. 2d 1096, 1100 (C.D. Cal. 2012) (important distinction between states that “include a reliance requirement in their consumer protection laws” and those that do not). These are just some of the “nuance[s]” of state law, far too numerous to address within the word limits of this petition, that render multistate classes uncertifiable. *Muehlbauer v. Gen. Motors Corp.*, No. 05-2676, 2009 WL 874511, at \*5 (N.D. Ill. Mar. 13, 2009).

For this reason alone, certification of the economic-loss classes was improper.

**B. Individualized Factual Issues Also Predominate.**

Certification was also improper because the economic-loss classes implicate highly individualized factual questions.

First, all of the claims turn on individualized questions related to defect, materiality, reliance, causation, injury and damages. Such variations likewise preclude class treatment.

Reliance, to take one example, makes classwide proof “a near-impossibility” under certain states’ laws due to its inherently individualized nature. *Brown v.*

*Electrolux Home Prods., Inc.*, 817 F.3d 1225, 1237 (11th Cir. 2016). Many consumer class members would have taken the VCDs even if they had known of the possible nitrosamine impurities—and therefore could not show reliance (or materiality/causation); indeed, several named plaintiffs (and one of plaintiffs’ experts) continued taking their VCDs after the recall. (*See* D.2008, 14 n.79.) That is not surprising since the FDA instructed consumers to “continue taking their medicine until they have a replacement product” (D.2040-1, 10-11) and quantified the risk of injury as perhaps 1 person in 8,000 who took the maximum dose for the maximum period of time (D.2008, 3 n.3; D.2009-12, Ex. 104). Moreover, many TPPs (and consumers) could not show any economic injury because, without the VCDs, they would have had to pay for “alternative hypertension medications,” which might have been more expensive. (D.2040-11, ¶ 63.) Determining which TPPs would have paid for which alternative medications requires TPP-by-TPP, if not patient-by-patient, analyses.

Plaintiffs’ blanket answer to all of these individualized issues was an expert’s opinion that all VCDs containing impurities were economically worthless—even if they worked as intended to lower blood pressure and did not meaningfully raise cancer risk—because there is no “‘legitimate’ supply curve” for prescription drugs that allegedly contain impurities. (*See* D.2040-1, 9.) This cure-all theory purportedly eliminates individualized issues by positing that all the

VCDs, regardless of dose, efficacy and level of impurity, were worth zero. But this theory is obviously wrong, as defendants’ experts explained in their reports and depositions. Indeed, the district court acknowledged defendants’ experts’ opinions that plaintiffs’ theory rested on “sophomoric economics and lack[ed] consideration of drug purchasers’ health rationales for continuing to ingest minimally contaminated drugs.” (Opinion 22-23.)

Still, despite recognizing that predominance turned on whose experts were right, the district court expressly refused to decide that question. (*Id.* 23.) According to the court, “choosing one theory over the other [would] drive[] a decision as to predominance that bounds too deeply into the province of the factfinder.” (*Id.*) That, too, was wrong. This Court has expressly held that “[w]eighing conflicting expert testimony at the certification stage is not only permissible; it may be integral to the rigorous analysis Rule 23 demands.” *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323 (3d Cir. 2008).<sup>4</sup> And a district court “may not decline to resolve a genuine legal or factual dispute”

---

<sup>4</sup> The court also erred in: (1) rejecting defendants’ experts’ opinions regarding the validity of the proposed medical-monitoring program (Opinion 74-75, 94-95); (2) failing to address the methodological problems with plaintiffs’ economist’s illogical theory that VCDs are worthless; and (3) excluding/rejecting defendants’ experts’ opinions that the VCDs did have value, even though the FDA repeatedly advised consumers to continue taking the medications because their benefits far outweighed any theoretical risk posed by nitrosamine impurities, refuting any claim that the medications had no value (*see id.* 77-82, 86-89).

relevant to class certification “because of concern for an overlap with the merits.” *Id.* at 324. Ignoring this instruction constitutes “err[or] as a matter of law.” *Id.* at 320.

A proper consideration of the experts’ opinions would have led the court to deny certification. Other courts that have assessed similar theories have rightly concluded that assigning zero value to a medication that “benefi[ted] many patients” is “not a defensible position.” *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 68-69 (S.D.N.Y. 2002) (rejecting use of no-value presumption and denying class certification); *see, e.g., Ctr. City Periodontists, P.C. v. Dentsply Int’l, Inc.*, 321 F.R.D. 193, 212 (E.D. Pa. 2017) (predominance lacking because “it is not true that [the dental device] had ‘zero value’”). And without judicial acceptance of that theory, a jury would have to evaluate the decision-making processes of millions of individual consumers and hundreds or thousands of TPPs to address issues such as reliance and causation.

The court also suggested that the use of “subclasses” could “account both for the variability in facts and the application of the facts to the required elements of each claim.” (Opinion 22.) But the subclasses proposed by plaintiffs and accepted by the court were intended to “account for state law variations,” not factual variations. (D.1748, 80; *see id.* 95.) There is obviously no reason to believe consumers from a group of states with similar legal regimes would all have similar

purchasing histories, decision-making inclinations or medical histories. *See Farrar & Farrar Dairy, Inc. v. Miller-St. Nazianz, Inc.*, 254 F.R.D. 68, 75-76 (E.D.N.C. 2008) (“[R]egardless of whether ... plaintiffs’ proposed subclassing can solve the ... predominance problem arising from differing state laws ... , it cannot address the predominance problem arising from ... individualized factual inquiries”).

Second, although the court repeatedly stated that a common course of conduct by defendants “grounds all of plaintiffs’ claims,” that is not true either. (Opinion 21; *see id.* 37 (defendants’ conduct “girds the entire litigation”).) As noted above, this case involves 428 distinct VCDs synthesized by different manufacturers of API, who used different chemical processes that are alleged to have created different amounts of NDMA and/or NDEA in different ways. (*See generally* D.1748, 8-38 (explaining different manufacturing processes as alleged by plaintiffs).) A jury could easily find one manufacturer’s process to be defective or negligent and another’s to be proper. Compounding the issue, plaintiffs have sued several different finished-dose manufacturers that incorporated valsartan with impurities into consumer-ready drugs. Each used different suppliers and took different steps to ensure purity, raising additional defendant-specific issues. (*See id.*) Courts have rejected far simpler class actions, recognizing that no jury could parse so many factual variations. *See, e.g., In re Bridgestone/Firestone, Inc.*, 288

F.3d 1012, 1019 (7th Cir. 2002) (granting 23(f) review and reversing class certification in part because case involved “67 specifications” of tires); *In re Ford Motor Co. Vehicle Paint Litig.*, 182 F.R.D. 214, 220 (E.D. La. 1998) (denying class certification in case involving “different models of vehicles, made of different materials, painted ... at different plants, using different paint formulae”); *City of St. Petersburg v. Total Containment, Inc.*, 265 F.R.D. 630, 636 (S.D. Fla. 2010) (predominance requirement was not satisfied where claims involved “different models ... manufactured by different companies at different times and at different locations”). The comparative maze of facts here should have weighed even more strongly against class treatment.<sup>5</sup>

In short, the certified economic-loss class spans every single state and pits millions of consumers and thousands of insurers against numerous manufacturers of different products, at different strengths and with different impurity levels. Common issues do not come close to predominating, and the district court erred in holding otherwise.

---

<sup>5</sup> Because plaintiffs have sued multiple defendants over different products with different alleged nitrosamine impurities, even commonality is not met. The district court’s contrary conclusion that plaintiffs satisfied this requirement by alleging that “defendants’ conduct of contaminating the VCDs ... caused plaintiffs’ economic loss” (Opinion 15) fails to grapple with these variations.

**C. A Class Action Is A Vastly Inferior Mechanism For Resolving The Dispute.**

All of the problems outlined above would combine to create a nightmare of a trial, a reality that the district court’s order meets with a rhetorical shrug that strongly suggests the certification order was meant to exert settlement pressure rather than to set the stage for an actual trial, as the trial court effectively admitted by explicitly invoking the prospect of settlement in its ruling. (Opinion 41.)

Rule 23(b)(3)’s “manageability” requirement “encompasses ‘the whole range of practical problems that may render the class action format inappropriate for a particular suit.’” *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 191 (3d Cir. 2001). A case of such “magnitude and complexity” that it “could not be tried” may not be certified. *Id.*

This is such a case. Plaintiffs proposed a three-phase trial in which all the economic-loss claims for both consumers and TPPs would “be jointly prosecuted in a single trial with a jury making findings on the legal claims, and the [c]ourt making findings on the equitable claims.” (D.1748-23, 3.) If necessary, a second phase would “determine the aggregate amount of non-compensatory damages and/or civil penalties,” a third phase would apportion damages, and a claims-administration process would allocate recovery. (*Id.* 6-8.)

A trial of this magnitude would be unmanageable at every stage. First there is the trial itself, which would involve 111 subclasses—so many that it took the

plaintiffs *67 pages just to list them*. (See D.1747-1; D.1747-2.) These subclasses advance five legal theories against 28 defendants from 10 different corporate families, spanning four different levels of the supply chain—API manufacturing, finished-dose manufacturing, wholesale and retail.<sup>6</sup> Dizzying numbers of witnesses and trial days are guaranteed, as are juror confusion and trial error.

Instructing the jury would be even more complicated. As other courts have held, “[i]f more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury.” *In re Am. Med. Sys.*, 75 F.3d 1069, 1085 (6th Cir. 1996). The task in this case would be orders of magnitude beyond “impossible.” The model jury instructions applicable to plaintiffs’ claims total approximately *1,200 pages*. (See D.2008-12, D.2008-13, D.2008-14, D.2008-15.) At a quick pace, reading one page every two minutes, it would take *40 hours*—a whole workweek—to instruct the jury. Once instructed, no human jury could possibly account for the “nuances” of the “multiple standards” and return an intelligent verdict. *Marshall v. H&R Block Tax Servs.*, 270 F.R.D. 400, 408 (S.D. Ill. 2010); *see also, e.g., Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1833, 2015 WL 3623005, at \*40 (E.D. Pa. June 10, 2015) (denying certification of

---

<sup>6</sup> The district court also overlooked jurisdictional and venue barriers to trying claims in 73 of the 93 consumer subclasses. *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). (D.2008, App. O.)

consumer and TPP class in part because “[p]laintiffs ... failed to demonstrate how the jury could be instructed in a manageable and accurate fashion”).<sup>7</sup>

Strikingly, plaintiffs conceded these manageability issues in their briefing below, encouraging the district court to “devise imaginative solutions” to rescue the massive classes. (D.2057, 5.) Among other things, plaintiffs suggested that the court could “sever a specific subclass or issue class or a discrete trial” or “advanc[e] ... discrete groupings or subclasses by defendant, state(s), claims, or issues.” (*Id.* 4.) They even suggested that the classes could exist for pretrial purposes only, followed by “severing and remanding [individual] cases.” (*Id.* 9.)

The district court did not even mention plaintiffs’ concession in its ruling; nor did it clarify whether it envisioned a single trial or some alternative procedure. To the extent it mentioned manageability, it waved the issue off, vaguely conceding that trial might be “onerous and [require] a steep climb of effort,” but that the district court’s “experience with the MDL” will guide the way. (Opinion 24.) In truth, nothing in the district court’s experience equips it for the epic proceeding that awaits. And accepting the district court’s “everything goes in an MDL” rationale would effectively dispense with Rule 23’s requirements in

---

<sup>7</sup> The district court’s extensive tables and comments on the parties’ state-law appendices illustrate the complexity of the issues and the impossibility that a jury receiving a week’s worth of oral instructions could ever keep them straight.

multidistrict litigation—an approach other appellate courts have condemned. *E.g.*, *Nat’l Prescription Opiate Litig.*, 976 F.3d at 673. In reality, the only explanation for the court’s ruling is that it does not actually envision any class trial at all. Like its refusal to hold bellwether personal injury trials (as sought by defendants), the district court certified this class to exert more settlement pressure on defendants, and not because it believed a class trial was feasible consistent with the requirements of Rule 23 and its due process underpinnings. That is not permissible under Rule 23 or consistent with the role and obligations of an MDL judge.

### **CONCLUSION**

For the forgoing reasons, the Court should grant the petition and reverse the class certification order.

Dated: February 22, 2023

Respectfully submitted,

By: /s/ Jessica Davidson Miller

Jessica Davidson Miller (Admitted to Practice in Maryland and the District of Columbia; Not Admitted in New York)

*Liaison Counsel for Manufacturer Defendants*  
SKADDEN, ARPS, SLATE, MEAGHER &  
FLOM LLP

One Manhattan West  
New York, NY 10001

Telephone: (212) 735-3000

Facsimile: (917) 777-2588

jessica.miller@skadden.com

*Attorney for Zhejiang Huahai Pharmaceutical  
Co., Ltd., Huahai U.S., Inc., Princeton*

*Pharmaceutical Inc., and Solco Healthcare U.S., LLC*

GREENBERG TRAURIG, LLP

/s/ Lori G. Cohen

Lori G. Cohen

Victoria Davis Lockard

Steven M. Harkins

Terminus 200

3333 Piedmont Road, N.E.

Suite 2500

Atlanta, Georgia 30305

Tel: (678) 553-2385

Fax: (678) 553-2386

[cohenl@gtlaw.com](mailto:cohenl@gtlaw.com)

[lockardv@gtlaw.com](mailto:lockardv@gtlaw.com)

[harkinss@gtlaw.com](mailto:harkinss@gtlaw.com)

Brian H. Rubenstein

1717 Arch Street

Suite 400

Philadelphia, Pennsylvania 19103

Tel: (215) 988-7864

Fax: (215) 689-4419

[rubensteinb@gtlaw.com](mailto:rubensteinb@gtlaw.com)

Gregory E. Ostfeld

77 West Wacker Drive,

Suite 3100

Chicago, Illinois 60601

Tel: (312) 476-5056

[ostfeldg@gtlaw.com](mailto:ostfeldg@gtlaw.com)

WALSH PIZZI O'REILLY FALANGA, LLP

/s/ Liza M. Walsh

Liza M. Walsh

Christine I. Gannon

Three Gateway Center

100 Mulberry Street

15th Floor

Newark, New Jersey 07102  
Tel: (973) 757-1100  
Fax: (973) 757-1090  
[lwalsh@walsh.law](mailto:lwalsh@walsh.law)  
[cannon@walsh.law](mailto:cannon@walsh.law)

*Attorneys for Teva Pharmaceuticals USA, Inc.,  
Teva Pharmaceutical Industries Ltd., Actavis  
Pharma, Inc., and Actavis LLC*

**HARDIN KUNDLA MCKEON & POLETT**  
Janet L. Poletto, Esq.  
Robert E. Blanton, Jr., Esq.  
673 Morris Ave.  
Springfield, New Jersey 07081  
Tel: (973) 912-5222  
Fax: (973) 912-9212  
Email: [jpoletto@hkmpp.com](mailto:jpoletto@hkmpp.com)  
Email: [rblanton@hkmpp.com](mailto:rblanton@hkmpp.com)

*Attorneys for Hetero USA Inc.*

**LEWIS BRISBOIS BISGAARD & SMITH  
LLP**

/s/ Walter H. Swayze, Esq.  
Walter H. Swayze, Esq.  
Andrew F. Albero, Esq.  
550 E. Swedesford Road, Suite 270  
Wayne, Pennsylvania 19087  
Tel: (215) 977-4100  
Fax: (215) 977-4101  
Email: [Pete.Swayze@lewisbrisbois.com](mailto:Pete.Swayze@lewisbrisbois.com)  
Email: [andrew.albero@lewisbrisbois.com](mailto:andrew.albero@lewisbrisbois.com)

*Attorneys for Camber Pharmaceuticals, Inc.*

**HILL WALLACK LLP**  
/s/ Eric Abraham  
Eric I. Abraham, Esq.  
William P. Murtha, Esq.

HILL WALLACK, LLP  
21 Roszel Road,  
Princeton, NJ 08543-5226  
(609) 734-6395  
[eabraham@hillwallack.com](mailto:eabraham@hillwallack.com)  
[wmurtha@hillwallack.com](mailto:wmurtha@hillwallack.com)

*Attorneys for Hetero Drugs Ltd. and  
Hetero Labs Ltd.*

/s/ Devora W. Allon, P.C.  
KIRKLAND & ELLIS LLP  
Jay P. Lefkowitz, P.C.  
Devora W. Allon, P.C.  
Alexia R. Brancato  
601 Lexington Avenue  
New York, New York 10022  
Tel: (212) 446-4970  
Fax: (212) 446-6460  
[Lefkowitz@kirkland.com](mailto:Lefkowitz@kirkland.com)  
[Devora.allon@kirkland.com](mailto:Devora.allon@kirkland.com)  
[Alexia.brancato@kirkland.com](mailto:Alexia.brancato@kirkland.com)

*Attorneys for Torrent Pharmaceuticals Ltd. and  
Torrent Pharma Inc.*

### **CERTIFICATE OF COMPLIANCE**

I certify that this petition complies with the type-volume limitation of Fed. R. App. P. 5(c) because it contains 5,188 words, as counted by Microsoft Word, the word processing software used to prepare this brief.

This petition also complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) & (6) because it has been set in a 14 point, proportionally spaced typeface (Times New Roman).

Dated: February 22, 2023

By: /s/ Jessica Davidson Miller

Jessica Davidson Miller (Admitted to Practice in Maryland and the District of Columbia; Not Admitted in New York)

*Liaison Counsel for Manufacturer Defendants*  
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

One Manhattan West

New York, NY 10001

Telephone: (212) 735-3000

Facsimile: (917) 777-2588

jessica.miller@skadden.com

*Attorney for Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Princeton Pharmaceutical Inc., and Solco Healthcare U.S., LLC*

**CERTIFICATE OF BAR MEMBERSHIP**

I certify, pursuant to Local Appellate Rule 46.1, that I am a member in good standing of the Bar of the United States Court of Appeals for the Third Circuit.

Dated: February 22, 2023

By: /s/ Jessica Davidson Miller

Jessica Davidson Miller (Admitted to Practice in Maryland and the District of Columbia; Not Admitted in New York)

*Liaison Counsel for Manufacturer Defendants*  
SKADDEN, ARPS, SLATE, MEAGHER &  
FLOM LLP

One Manhattan West

New York, NY 10001

Telephone: (212) 735-3000

Facsimile: (917) 777-2588

jessica.miller@skadden.com

*Attorney for Zhejiang Huahai Pharmaceutical Co., Ltd., Huahai U.S., Inc., Princeton Pharmaceutical Inc., and Solco Healthcare U.S., LLC*

## **CERTIFICATE OF SERVICE**

I certify that, on February 22, 2023, I filed the foregoing Rule 23(f) Petition for Permission to Appeal, with the Clerk of the Court using the CM/ECF system.

A true and correct copy was sent via electronic mail per agreement of the parties to the following counsel of record:

Adam Slater Christopher Geddis MAZIE, SLATER, KATZ & FREEMAN, LLC 103 Eisenhower Pkwy, 2nd Flr. Roseland, NJ 07068 Phone: (973) 228-9898 <a href="mailto:aslater@mazieslater.com">aslater@mazieslater.com</a> <a href="mailto:cgeddis@mazieslater.com">cgeddis@mazieslater.com</a>	Ruben Honik HONIK LLC 1515 Market Street, Suite 1100 Philadelphia, PA 19102 Phone: (267) 435-1300 <a href="mailto:ruben@honiklaw.com">ruben@honiklaw.com</a>
Daniel Nigh LEVIN, PAPANTONIO, THOMAS, MITCHELL RAFFERTY & PROCTOR, P.A. 316 South Baylen Street Pensacola, FL 32502 Phone: (850) 435-7013 <a href="mailto:dnigh@levinlaw.com">dnigh@levinlaw.com</a>	Conlee S. Whiteley David J. Stanoch Layne C. Hilton KANNER & WHITELEY, LLC 701 Camp Street New Orleans, LA 70130 Phone: (504)-524-5777 <a href="mailto:c.whiteley@kanner-law.com">c.whiteley@kanner-law.com</a>
John R. Davis SLACK DAVIS SANGER, LLP 6001 Bold Ruler Way, Suite 100 Austin, TX 78746 Tel.: 512-795-8686 Fax: 512-795-8787 <a href="mailto:jdavis@slackdavis.com">jdavis@slackdavis.com</a>	Jorge Mestre RIVERO MESTRE LLP 2525 Ponce de Leon Blvd., Suite 1000 Miami, FL 33134 Phone (305) 445-2500 <a href="mailto:ariveros@riveromestre.com">ariveros@riveromestre.com</a>
Rachel Geman <a href="mailto:rgeman@lchb.com">rgeman@lchb.com</a> Kartik S. Madiraju <a href="mailto:kmadiraju@lchb.com">kmadiraju@lchb.com</a> LIEFF CABRASER HEIMANN & BERNSTEIN, LLP	Nicholas Migliaccio <a href="mailto:nmigliaccio@classlawdc.com">nmigliaccio@classlawdc.com</a> Jason Rathod <a href="mailto:jrathod@classlawdc.com">jrathod@classlawdc.com</a> Mark Patronella <a href="mailto:mpatronella@classlawdc.com">mpatronella@classlawdc.com</a>

250 Hudson Street, 8 <sup>th</sup> Floor New York, NY 10013-1413 Telephone: (212) 355-9500 Facsimile: (212) 355-9592	MIGLIACCIO & RATHOD LLP 412 H Street NE, Suite 302 Washington, DC 20002 Telephone: (202) 470-3520 Facsimile: (202) 800-2730
	Gregory P. Hansel PRETI, FLAHERTY, BELIVEAU & PACHIOS, CHARTERED, LLP One City Center P.O. Box 9546 Portland, ME 04112 Phone: (207) 791-3000 <a href="mailto:ghansel@preti.com">ghansel@preti.com</a>
<i>MDL plaintiffs' co-lead counsel and co-lead class counsel</i>	

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP Clem C. Trischler Jason M. Reefer Frank H. Stoy 38th Floor, One Oxford Centre Pittsburgh, Pennsylvania 15219 Tel: (412) 263-2000 Fax: (412) 263-2001 <a href="mailto:cct@pietragallo.com">cct@pietragallo.com</a> <a href="mailto:jmr@pietragallo.com">jmr@pietragallo.com</a> <a href="mailto:fhs@pietragallo.com">fhs@pietragallo.com</a> <i>Attorneys for Mylan Laboratories, Ltd. and Mylan Pharmaceuticals, Inc.</i>	MORGAN, LEWIS & BOCKIUS LLP John P. Lavelle, Jr. 502 Carnegie Center Princeton, New Jersey 08540 Tel.: (609) 919-6688 Fax: (609) 919-6701 Email: <a href="mailto:John.lavelle@morganlewis.com">John.lavelle@morganlewis.com</a>  John K. Gisleson One Oxford Centre, Thirty-Second Floor Pittsburgh, Pennsylvania 15219 Tel. (412) 560-3300 Fax (412) 560-70001 <a href="mailto:john.gisleson@morganlewis.com">john.gisleson@morganlewis.com</a>  <i>Attorneys for Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC</i>
LEWIS BRISBOIS BISGAARD & SMITH LLP Walter H. Swayze, III Andrew F. Albero 550 E. Swedesford Road, Suite 270 Wayne, Pennsylvania 19087	BARNES & THORNBURG LLP Sarah E. Johnston Liaison Counsel for Retailer Defendants Kristen L. Richer 2029 Century Park East Suite 300

<p>Tel: (215) 977-4100  Fax: (215) 977-4101  <a href="mailto:Pete.Swayze@lewisbrisbois.com">Pete.Swayze@lewisbrisbois.com</a>  <a href="mailto:Andrew.Albero@lewisbrisbois.com">Andrew.Albero@lewisbrisbois.com</a>  Attorneys for The Kroger Co.</p>	<p>Los Angeles, California 90067  Tel.: (310) 284-3880  Fax: (310) 284-3894  <a href="mailto:sarah.johnston@btlaw.com">sarah.johnston@btlaw.com</a>  <a href="mailto:kristen.richer@btlaw.com">kristen.richer@btlaw.com</a></p> <p>Kara Kapke  11 S Meridian St.  Indianapolis, Indiana 46204  Tel. (317) 236-1313  Fax (317) 231-7433  <a href="mailto:kara.kapke@btlaw.com">kara.kapke@btlaw.com</a>  Attorneys for CVS Pharmacy, Inc.,  (incorrectly named as CVS Health  Corporation), Rite Aid Corporation,  Walgreen Co. (incorrectly named as  Walgreens Co.), and Walmart Inc.  (incorrectly named as Walmart Stores,  Inc.)</p>
<p>HUSCH BLACKWELL LLP  Matt Knepper  James Spung  190 Carondelet Plaza  Suite 600  St. Louis, Missouri 63105  Tel.: (314) 480-1500  Fax: (314) 480-1505  <a href="mailto:Matt.knepper@huschblackwell.com">Matt.knepper@huschblackwell.com</a>  <a href="mailto:James.spung@huschblackwell.com">James.spung@huschblackwell.com</a>  Attorneys for Express Scripts, Inc.</p>	<p>DORSEY &amp; WHITNEY LLP  Roxanna Gonzalez  50 South Sixth Street  Suite 1500  Minneapolis, MN 55402-1498  Tel.: (612) 492-6518  Fax: (952) 516-5739  <a href="mailto:gonzalez.roxanna@dorsey.com">gonzalez.roxanna@dorsey.com</a>  Attorneys for Optum, Inc. and Optum  Rx</p>
<p>BUCHANAN INGERSOLL &amp;  ROONEY PC  Jonathan D. Janow  Jason R. Parish  1700 K Street NW  Suite 300  Washington, DC 20006  Tel.: (202) 452-7940  Fax: (202) 452-7989  <a href="mailto:Jonathan.Janow@bipc.com">Jonathan.Janow@bipc.com</a></p>	<p>ULMER &amp; BERNE LLP  Jeffrey D. Geoppinger  Liaison Counsel for Wholesalers  312 Walnut Street, Suite 1400  Cincinnati, OH 45202-2409  Tel.: (513) 698-5038  Fax: (513) 698-5039  Email: <a href="mailto:jgeoppinger@ulmer.com">jgeoppinger@ulmer.com</a>  Counsel for AmerisourceBergen  Corporation</p>

<a href="mailto:Jason.Parish@bipc.com">Jason.Parish@bipc.com</a> Attorneys for Albertson's LLC	
CROWELL & MORING Andrew D. Kaplan Daniel T. Campbell Marie S. Dennis Emily G. Tucker Luke J. Bresnahan 1001 Pennsylvania Avenue NW Washington, D.C. 20004 Tel.: (202) 624-1000 Fax: (202) 628-5116 Email: <a href="mailto:akaplan@crowell.com">akaplan@crowell.com</a> Email: <a href="mailto:dcampbell@crowell.com">dcampbell@crowell.com</a> Email: <a href="mailto:mdennis@crowell.com">mdennis@crowell.com</a> Email: <a href="mailto:etucker@crowell.com">etucker@crowell.com</a> Email: <a href="mailto:lbresnahan@crowell.com">lbresnahan@crowell.com</a> Counsel for Cardinal Health, Inc.	NORTON ROSE FULBRIGHT US LLP D'Lesli M. Davis Ellie K. Norris 2200 Ross Avenue, Suite 3600 Dallas, TX 75201-7932 Tel: (214) 855-8221 Fax: (214) 855-8200 Email: <a href="mailto:dlesli.davis@nortonrosefulbright.com">dlesli.davis@nortonrosefulbright.com</a> Email: <a href="mailto:ellie.norris@nortonrosefulbright.com">ellie.norris@nortonrosefulbright.com</a> Counsel for McKesson Corporation

Dated: February 22, 2023

By: /s/ Jessica Davidson Miller

Jessica Davidson Miller (Admitted to Practice in  
Maryland and the District of Columbia; Not  
Admitted in New York)

*Liaison Counsel for Manufacturer Defendants*  
SKADDEN, ARPS, SLATE, MEAGHER &  
FLOM LLP

One Manhattan West

New York, NY 10001

Telephone: (212) 735-3000

Facsimile: (917) 777-2588

[jessica.miller@skadden.com](mailto:jessica.miller@skadden.com)

*Attorney for Zhejiang Huahai Pharmaceutical Co.,  
Ltd., Huahai U.S., Inc., Princeton Pharmaceutical  
Inc., and Solco Healthcare U.S., LLC*